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|   |             |                      |                              |                  |
|---|-------------|----------------------|------------------------------|------------------|
| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
| 10/632,061  | 07/31/2003  | Robert E. Richard    | 02-321                       | 9972             |
| 27774 7590 04/17/2007<br>MAYER & WILLIAMS PC<br>251 NORTH AVENUE WEST<br>2ND FLOOR<br>WESTFIELD, NJ 07090 |             |                      | EXAMINER<br>SIMMONS, CHRIS E |                  |
|   |             |                      | ART UNIT                     | PAPER NUMBER     |
|   |             |                      | 1609                         |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE            | DELIVERY MODE                |                  |
| 3 MONTHS  |             | 04/17/2007           | PAPER                        |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/632,061

Applicant(s)

RICHARD ET AL.

Examiner

Chris E. Simmons

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/22/2005 ) 11/20/2004
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Election Acknowledgement**

Applicant's election, without mention of being in traverse, of the following species is acknowledged:

a stent is elected  
a poly(methyl acrylate) block is elected.  
a substituted polystyrene block is elected.  
a poly(methyl methacrylate) block is elected.  
a triblock copolymer is elected.  
a graft copolymer is elected.  
a supplemental polymer is elected.

The election requirement is, therefore, made final.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-7, and 9-26 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Pinchuk et al (US 2002/0107330 A1 -- August 8 2002; herein referred to as '330).

The instant claims are directed to an implantable or insertable medical device comprising a therapeutic agent and an acrylic copolymer which comprises hard units and rubbery units that controls the release of said agent.

'330 discloses an intravascular or intervascular medical device (e.g., a stent; ¶ 15) comprising a therapeutic agent-releasing biocompatible block polymer, said polymer is a copolymer that may be linear triblock (¶ 28) or branched (¶ 32), said copolymer comprising a therapeutic agent (e.g., heparin; ¶ 62), elastomeric blocks (e.g., polyolefins; ¶ 33 and claim 42) and thermoplastic blocks (e.g., vinyl aromatic blocks or methacrylate blocks (¶ 8 and claim 44), especially poly(methyl methacrylate) (¶ 8 claim 45) ) (See abstract, ¶ 177-178.) The poly(methyl acrylate) in instant application is defined as a polyolefin due to alkene group in the methyl acrylate monomer.

'330 discloses the device further comprising a polymer or copolymer layer that may contain the biocompatible block copolymer (Claim 54) or may not contain the biocompatible block copolymer (Claim 55).

As defined in the instant application, rubbery blocks have a glass transition temperature ( $T_g$ ) that is less than ambient temperature ( $25^\circ - 45^\circ\text{C}$ , more specifically  $37^\circ\text{C}$ ) and hard blocks have a  $T_g$  greater than ambient temperature.

### **35 U.S.C. 103**

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 8 is rejected under 35 USC 103(a) as being unpatentable over Pinchuk et al (US 2002/0107330 A1 -- August 8 2002; herein referred to as '330) in view of Van Dijk et al (WO/2000/061203; herein referred to as '203).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an

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invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

'330 discloses limitations as explained above.

'330 does not disclose expressly an elongation at break of at least 25% at ambient temperature.

'203 discloses a stent with elongation of at least 8% (Abstract).

'330 and '203 are analogous art because they are from the same field of endeavor viz biomedical stents.

At the time of the invention it would have been obvious to a person of ordinary skill in the art to create a biomedical stent with an elongation of break of at least 8%.

The suggestion/motivation for doing so would have been increase the flexibility of a biomedical stent to facilitate conformity to vessel or organ contour.

Therefore it would have been obvious to combine '330 with '203 to obtain the claimed invention as specified in claim 8.

7. Claim 27 is rejected under 35 USC 103(a) as being unpatentable over Pinchuk et al (US 2002/0107330 A1 -- August 8 2002; herein referred to as '330) in view of Ding et al (PS Patent 5,837,313 -- herein referred to '313).

'330 discloses limitations as explained above.

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'330 does not disclose expressly sterilization by using radiation.

'313 discloses sterilization of a stent prosthesis by exposing to radiation (Abstract).

'330 and '313 are analogous art because they are from the same field of endeavor viz stents coated with therapeutic agent-containing polymers.

At the time of the invention it would have been obvious to a person of ordinary skill in the art to sterilize a stent coated with a therapeutic agent-containing polymer by exposing to radiation.

The suggestion/motivation for doing so would have been to provide a drug-eluting stent that is sterile and safe for the patient.

Therefore it would have been obvious to combine '330 with '313 to obtain the claimed invention as specified in claim 27.

### ***Conclusion***

1. It is noted that the following are pertinent art in relation to instant application;

however, not relied upon in current rejection:

Dinh et al (US Patent 6187370)

2. No claims are allowed.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on (571) 272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chris Simmons/ CES



**VICKIE KIM**  
**PRIMARY EXAMINER**